PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Wolf, et al. SERIAL NO.: 09/524,716 FILING DATE: March 14, 2000 TITLE: **CARBOHYDRATE SYSTEM AND A METHOD FOR PROVIDING NUTRITION TO A DIABETIC**	EXAMINER: Choi, F. ART UNIT: 1616 DOCKET NO.: 6671.US.O1 I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being sent by facsimile transmission to (703) 308-4556 addressed to the Assistant Commissioner for Patents, Box RCE, Washington, D.C., 20231 on the date shown below. Sarah Mayhew 05/28/02 Sarah Mayhew Date

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REMARKS

The Inventors are filing a RCE in response to the Final Office Action mailed April 4, 2002 that cited new prior art. Claims 18, 19 and 22 were allowed in the Final Office Action. Claims 1-17, 20, 21, 23 and 24 remain active in this application. In this amendment, the Inventors have cancelled claims 1-5, 23 and 24; amended claims 6 and 11; and added claims 25-27. Support for the amendments to the percent of calories from carbohydrate in claims 6 and 11 may be found on page 15, lines 20 through 23, Table 5, claims 9 and 16. Support for the amendments to the percent of calories from fat in claims 6 and 11 may be found on page 16, lines 13 through 15, Table 5, claims 7 and 14. Support for new claims to the method for blunting the postprandial glycemic response may be found on page 5, lines 22 through 24, Examples V and VI.

Claims 1-17, 20, 21, 23 and 24 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under U.S.C. 103(a) as obvious over Kaufman. Kaufman teaches the use of a carbohydrate system containing a slowly absorbed complex carbohydrate from 10 to 30% of the carbohydrate system, a rapidly absorbed complex carbohydrate from 14 to 40% of the carbohydrate system and a simple sugar from 0 to 30% of the carbohydrate system. A therapeutic food including this carbohydrate system diminishes the fluctuations in blood sugar levels and prevents

hypoglycemic episodes in diabetics. Kaufman further limits the use f simple sugar component (other than fructose) to less than 6% of the total carbohydrat system.

The Kaufman carbohydrate system requires three components: slowly absorbed complex carbohydrate, a rapidly absorbed complex carbohydrate and a simple sugar as a sweetening agent. The slowly absorbed complex carbohydrate is defined as being slowly digested and is not completely metabolized even after 3-4 hours. The preferred slowly absorbed carbohydrate is uncooked cornstarch. The more rapidly absorbed complex carbohydrate refers to macromolecular carbohydrates including starches, polydextrose and other polysaccharides. The term sweetening agent refers to simple sugars (sucrose, lactose, galactose and fructose), sugar alcohols (sorbitol, maltitiol) and artificial sweeteners (aspartame, saccharin).

The claimed carbohydrate mixture includes from 5 to 50 % of the carbohydrate mixture as a source of fructose in combination with at least one source of readily digestible glucose polymers making up 50 to 95% of the carbohydrate mixture. Readily digestible glucose polymers (a.k.a. Kaufman's rapidly absorbed complex carbohydrate) are defined as rapidly digested hydrolyzed starches and glucose oligomers (page 7, line 5). The claimed carbohydrate system of the instant invention does not require the slowly absorbed complex carbohydrate. Yet the claimed carbohydrate system results in the same clinical effect as the Kaufman carbohydrate system. An unexpected advantage of the claimed carbohydrate system is that a nutritional formula may contain a higher percentage of rapidly digested carbohydrates, which are typically limited in a diabetics diet, and produce a lower glycemic response than expected. This is exemplified by the presence of readily digestible glucose polymers at 50 to 95% of the carbohydrate system, while Kaufman limits the rapidly absorbed complex carbohydrate component to 14 to 40% of the carbohydrate system. Further, the optional indigestible oligosaccharides and nonabsorbent carbohydrates of the claimed carbohydrate system are resistant to endogenous digestion therefore do not meet the definition of Kaufman's slowly absorbed complex carbohydrates (page 8, lines 1-10).

The inventors have amended claim 6 to further define the carbohydrate system to "consist essentially of" the fructose and digestible glucose polymer, thereby further differentiating the claim from the carbohydrate system of Kaufman. The Inventors request that the Examiner remove the above rejection from claims 6-17, 20 and 21.

Claims 1-17 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternativ , under 35 U.S.C. 103(a) as obvious ver Paul et al. (US. Pat. 5,292,538).

Paul discl ses a composition to support an anabolic physiological state that comprises a blend of simple sugars and more compl x carbohydrates, partially hydrolyzed protein and at least magnesium in the form of an amino acid chelate. The carbohydrate source is a blend of about 5-45% fructose and about 55-95% glucose by weight. Claims 1-5 have been cancelled rendering this rejection to claims 1-5 moot.

The Paul composition is designed to support a patient under physiological stress that often accompanies protein calorie malnutrition, strenuous physical exercise, physical trauma, burn injury, surgical trauma, malnutrition, maldigestion, malabsorption, hyperthyroidism, chemotherapy, radiation therapy, anorexia, cachexia, short bowel syndrome, old age and sepsis. These patients are under physiological stress such that their bodies are burning large amounts of energy and they are depleting their bodies of fluids, and minerals. This is not the metabolic state of a typical diabetic.

The Paul composition supports the anabolic state by adding partially hydrolyzed protein to a formulation often utilized as an oral rehydration solution, that is carbohydrate and electrolytes. All of the required amounts of each ingredient are described as "parts by weight". In order to better evaluate the claims of the instant invention, which are in % total calories, we have taken Paul Formulations I-VIII and converted the gram weights into % total calories. Using standard conversion factors for protein (4 kcal/gm), fat (9 kcal/gm) and carbohydrate (4 kcal/gm), a table has been generated below listing the percentage of carbohydrate, protein and fat based on total calories.

Paul et al. Formulations I-VIII (% of total Kcal)

	I	II	III	IV	V	VI	VII	VIII
	(% of total kcal)							
Carbohydrate (4 kcal/gm)	81%	76%	93%	62%	86%	84%	77%	75%
Protein (4 kcal/gm)	15%	22%	7%	26%	14%	14%	17%	25%
Fat (9 kcal/gm)	3%	10%	-	12%	-	2%	5%	-
Total kcal	357	476	300	377	560	333	346	160

The Paul formulas contain very high level of carbohydrates and very low level of fat. These types of formulas would not be found appropriate for the diabetic population by one practicing in the field. The diabetic formula is typically higher fat and lower carbohydrate. Claims 6 and 11 have been amended to include dependent claims 7,9 and 14,16, respectively, to further define the appropriate carbohydrate and fat

contribution for a diabetic formulation. The table below compares the percentage of total calories for the claims of the instant invention and the Paul formulati ns.

Macronutrient ranges (% of t tal kcal)

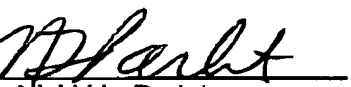
	Paul Formulations I-VIII	Instant Invention
Carbohydrate	62 – 93%	25 – 55%
Protein	7 – 26%	10 – 35%
Fat	0 – 12%	25 – 37%

The Examiner will note that there are significant differences between the two formulations and one in the art would not utilize the diabetic formulation in an anabolic patient. Inventors request that the Examiner remove the rejection for claims 6-17, 20 and 21.

Claims 1-17, 20, 21,23, and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al in view of Kaufman. As the Examiner has noted, Paul utilized fructose in their composition because fructose promotes a more rapid emptying of the stomach thereby getting the needed nutrients to the GI track of the stressed patient rapidly. Rapid emptying of the stomach is counter to the goal of the diabetic formulas of the instant invention where a prolonged release of nutrients into the GI track helps to delay or blunt the glycemic response. Kaufman's method of blunting the glycemic response is to utilize complex carbohydrates that take varying times to break down in the GI track.

One knowledgeable in the art would not expect the rapidly digested carbohydrate (fructose) and hydrolyzed starch of Paul to blunt the glycemic response in the same way as the slowly digested carbohydrate system of Kaufman. Since Kaufman teaches that a slowly digested carbohydrate is needed in addition to the sweetener and hydrolyzed starch, they would not be motivated to add only the Paul carbohydrate system to a nutritional designed for diabetics. The Inventors request that the Examiner remove the above rejection for claims 6-17, 20 and 21.

Respectfully submitted,



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REDLINED CLAIMS

6. (twice amended) A nutritional product comprising:

a) a carbohydrate mixture comprising from about 25% to about [60%] 55% of the total calories of the product, said carbohydrate mixture [comprising] consisting essentially of:

i) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the carbohydrate mixture: and

iv) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the carbohydrate mixture,

b) a source of fat comprising [less than about 37%] from about 25 to about 37% of the total calories of the product; and

d) a source of protein comprising from about 10% to about 35% of the total calories of the product.

11. (amended) A nutritional product comprising:

a) a carbohydrate mixture comprising from about 25% to about [60%] 55% of the total calories of the product, said carbohydrate mixture comprising :

iii) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the carbohydrate mixture,

iv) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the carbohydrate mixture,

v) less than about 20 wt/wt% of the carbohydrate system as nonabsorbent carbohydrates,

b) a source of fat comprising [less than about 37%] from about 25 to about 37% of the total calories of the product; and

c) a source of protein comprising from about 10% to about 35% of the total calories of the product.